The Pharmaceutical Compliance Monitor

Combating the Counterfeiting of Pharmaceuticals: Bringing the Criminals to Justice

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Counterfeit pharmaceuticals are disturbingly prevalent. A November 2003 article in Chemical & Engineering News magazine noted that "counterfeit Procrit, an antianemia drug, placed at-risk patients severely ill with cancer and AIDS, and counterfeit Epogen caused grave medical complications for organ transplant recipients and patients with end-stage kidney disease." In 2006, the FDA notified consumers about counterfeit blood glucose test trips being sold in the United States. According to Counterfeit Drugs and National Security, global counterfeit drug sales in 2010 totaled more than $70 billion, a 90% increase since 2005.

Knowingly trafficking in counterfeit products is a crime in the United States. A pharmaceutical company faced with a counterfeiting problem must take decisive action in order to protect consumers from potentially dangerous fakes, defend the company's brand, and deter others from engaging in similar activity. However, because law enforcement agencies have limited resources and many competing priorities, not all criminal referrals of counterfeit products are successful. Knowing the benefits of pursuing a criminal referral in these circumstances and being armed with best practices can maximize the prospects that law enforcement will investigate and prosecute those responsible for this serious crime.

A company can damage its reputation and jeopardize the successful prosecution of future claims by making a weak referral, so it is vitally important for pharmaceutical companies to understand the factors weighed by law enforcement when deciding to pursue criminal charges. The number one consideration for law enforcement is whether the counterfeit product presents a health and safety risk to the public. As most counterfeit pharmaceuticals are highly dangerous, law enforcement must also regard the strength and integrity of the evidence. Companies must therefore consider questions such as: what evidence can be developed on the issue of whether the trafficker knew that it was trafficking in counterfeit products? Have appropriate chain of custody protocols been followed in connection with having obtained any of the counterfeit products themselves? Does the scientific analysis absolutely confirm that the products are counterfeit? (A company's credibility might not withstand a false positive on this.) Finally, many enforcement agencies and prosecutors' offices will not consider a case if the dollar volume of the counterfeit trafficking is below a pre-set threshold. While these thresholds might be relaxed in situations where there are significant health and safety concerns, it is nonetheless an important factor.

Another consideration pharmaceutical companies must take into account is which law enforcement agency is the most appropriate organization to handle the referral. The Food and Drug Administration has an Office of Criminal Investigations with special agents who investigate these crimes. There are also agents from the Federal Bureau of Investigation and the Department of Homeland Security dedicated to investigating intellectual property crimes,

including crimes associated with counterfeiting pharmaceuticals. Many of the United States Attorney's Offices ("USAO") in the United States have Computer Hacking and Intellectual Property ("CHIP") units with federal prosecutors devoted to prosecuting counterfeit crimes. Where a specific CHIP Unit does not exist, a USAO may have a federal prosecutor designated as a CHIP prosecutor. State prosecuting authorities throughout the country also prosecute counterfeiting crimes at the State level.

While there are many avenues through which companies can prosecute counterfeiting crimes, agencies and prosecuting offices in certain jurisdictions may be more amenable to pursuing counterfeiting cases than others. Each office has limited resources and its own competing priorities that affect which cases it is able to take and an individual agency may have to weigh whether a counterfeiting case would preclude its pursuit of other pressing crimes, such as terrorism, drug trafficking, and financial fraud. Thus, it is important to weigh the pros and cons of a particular agency and prosecuting office against the specific claim when deciding where to make a criminal referral.

Once the decision has been made pursue a referral, a pharmaceutical company must compile a referral package to share with law enforcement. This package usually consists of an investigative report that describes, in a clear and concise manner, the key evidence demonstrating that a person or entity knowingly trafficked in counterfeit pharmaceutical products. The report should include essential documents, such as evidence about the entities involved in the transactions, important witness interviews, analyses showing the products are counterfeit, and known health and safety risks of the counterfeited product. A referral meeting should be also scheduled. During this time company representatives will have the opportunity to further highlight the key evidence, describe in further detail the health and safety risks associated with the counterfeit products (usually through a company scientist or investigator), and, perhaps most importantly, demonstrate their commitment to supporting the referral. If the referral is "silver-plattered" in this way, the chances of a successful referral are greatly enhanced. If law enforcement opens a formal case after receiving the referral, the company will be expected to continue to provide support to the agents and prosecutors. This could take the form of further interviews of company witnesses, additional evidence gathering, and assistance in making company witnesses available for grand jury testimony or testimony at trial.

Federal law preserves various rights for a victim in a criminal case. If a conviction is obtained through trial or plea, the company is authorized by law to submit a victim impact statement, either in writing or in person during the sentencing hearing. The victim impact statement should summarize the harm to the company, including the harm to the company's brand because of the health and safety risks caused by the counterfeit pharmaceutical, and also the time and expense associated with company's investigation.

The company will also be entitled to restitution, which is mandatory in counterfeiting crimes, and should consult with the prosecutor about the appropriate measure of restitution. In the event that there are insufficient assets to satisfy a restitution award, the company may convert the restitution award into a civil judgment, and enforce it just at it would any other judgment.

Conviction through a plea agreement may afford the company one additional opportunity: the chance to interview the defendant after he has plead guilty but before sentencing. Defendants are motivated in these circumstances to answer questions by the victim company, so the defendant may tell the judge at sentencing that he or she has cooperated fully with the victim company. Such interviews may yield helpful intelligence relating to the manufacture, supply, and distribution of counterfeit pharmaceuticals.

Deterrence is the ultimate goal of any effort to refer the counterfeiting of pharmaceutical products to law enforcement. In these difficult economic times, it is especially important for a company to consider the impact on company resources when deciding how to combat the counterfeiting of its products. To that end, the impact of a criminal referral is often much greater than a comparable civil case. While there is certainly time and expense associated with preparing, making, and then supporting the referral, these expenditures typically pale in comparison to the time and expense associated with civil litigation, especially that associated with civil discovery and motion practice. Moreover, convictions, jail sentences, and forfeitures of assets provide much greater deterrence than a civil judgment (especially one that may be uncollectable), and indeed the mandatory restitution order can be converted into the civil judgment, ultimately putting the company in the same position to collect as if civil litigation had been pursued. For these reasons, it is strongly recommended that pharmaceutical companies victimized by the counterfeiting of its products consider making a criminal referral, in the appropriate cases, to combat this significant problem.

About the Author

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